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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,322	08/22/2001	Phuong Grace Dang	452005-13	1448

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,322	DANG ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments and Applicant's Arguments received on March 29, 2004 is acknowledged. Claims 1-30 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites, "said pharmaceutically effective amount being one half the daily dosage" which is unclear. Firstly it is unclear what the limitation intends to convey. Secondly, if the daily dosage is cut in half, how can it be an effective amount? Further clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1-2 and 4-5 under 35 U.S.C. 103(a) as being unpatentable over Denick et al (4,758,424) in view of JP 64007786 is maintained.

Denick et al teach a chewable cough tablet containing guaifenesin (100mg) and pharmaceutical excipients. See example 5.

Denick et al do not teach the incorporation of carbetapentane tannate.

JP teaches the use of carbetapentane tannate as a non-irritant cough suppressor.

It would have been obvious to one of ordinary skill at the time the invention was made to combine the teaching of Denick et al and JP and further incorporate carbetapentane tannate. One would be motivated to do so since JP teaches that carbetapentane tannate is a cough suppressor and Denick teaches a cough tablet. Therefore, one would be motivated to add a second cough agent to provide an additive effect since both drugs are taught to be cough agents and are utilized in the art for the same purpose.

Response to Arguments

Applicant argues that the examiner is using an "obvious to try" approach. Applicant argues that the examiner has not considered Denick et al as a whole. It is argued that Denick is directed to magnesium silicates adsorbates that are useful in masking the bitter taste of medicaments. Applicant argues there is not motivation to add JP's carbetapentane tannate to Denick's guaifenesin since JP teaches that carbetapentane tannate is tasteless.

Applicant's arguments have been fully considered but they are not persuasive. It is the examiner's position that the motivation to combine the references is that one would expect an additive effect by combining two known cough agents, absent unexpected resulting proving a synergistic effect. Denick teaches the known use of guaifenesin for suppressing cough in a taste masked product. Therefore, one would be

motivated to add the tasteless carbetapentane tannate not only for its cough suppression abilities but also for the fact that it will not destroy the palatable guaifenesin tablet prepared by Denick et al.

In regards to applicant's arguments that the references are wholly concerned with a different problem, the examiner points out that the use of a patent is not limited to what the patentees describe as their invention or the problems with which they are concerned, i.e. taste masking. They are part of the literature of all they contain, i.e. the teaching of guaifenesin in a cough tablet. See In re Heck.

The rejection of claims 1-6 under 35 U.S.C. 103(a) as being unpatentable over WO 96/22762 by itself or in view of Chopdekar et al (5,663,415) is maintained.

WO teaches a taste-masked pharmaceutical composition. Example II teaches a syrup composition containing 0.1323% dextromethorphan HBr, 1.3230% guaifenesin, and other pharmaceutical excipients. Examples of antitussives taught are dextromethorphan, cholpendianol, carbetapentane, etc. and their salts. See page 4, lines 24-29. The reference also teaches the method of reducing or abating the symptoms associated with the common cold, respiratory disorders, etc. see page 1, lines 33-36. WO teaches tablets or liquid dosage forms. See page 5, lines 25-27.

WO does not exemplify the inclusion of carbetapentane tannate.

Chopdekar et al teach antihistamine tannates since this form is stable and may be administered in its form without any side effects. See column 1, lines 15-18. The antihistamine reacted with the tannic acid may be carbetapentane, among others. See column 3, line 3.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to substitute dextromethorphan with carbetapentane in WO's example II. One would be motivated to do so with the expectation of similar results since WO teaches that both dextromethorphan and carbetapentane are antitussives. Therefore, it is deemed prima facie obvious to substitute one functional equivalent agent with another equivalent agent since both are known in the art for the same functional purpose.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the teachings of Chopdekar et al and utilize the tannate salt of carbetapentane. One would be motivated to do so since Chopdekar teaches the tannate salt form is more stable and has less side effects. Therefore, one would be motivated to use the tannate form to yield a stable composition with less side effects when the composition is administered. Further, one would expect similar results since WO teaches that the pharmaceutical acceptable salts of the antitussives are suitable for use in the composition.

Response to Arguments

Applicant argues that Kupper is directed to taste making and the examiner ignores this fact. The applicant recognizes that examples II teaches a syrup that contains dextromethophan hydrobromide and guaifenesin and that Kupper teaches dextromethophan and carbetapentane as antitussives. Applicant argues that hydrobromide and tannate are not functional equivalents. Applicant argues that neither reference exemplifies carbetapentane tannate.

Applicant's arguments have been fully considered but they are not persuasive. It is the examiner's position that the motivation to combine the references since Kupper teaches a composition containing both an expectorant, i.e. instant guaifenesin and an antitussive, dextromethophan. Further, Kupper recognizes that carbetapentane is also an antitussive. From this teaching alone, Kupper teaches the functional equivalence of the instant antitussive and dextromethophan. Applicant has not submitted any unexpected evidence to dispute and overcome the obviousness rejection.

Secondly, the examiner is not contending that hydrobromides and tannates are functional equivalents nor did the rejection state that Kupper teaches the instant salt. Thus, the examiner relies on the secondary reference to teach the instant tannate salt. Chopdekar teaches the tannate salt is more stable and reduces side effect. Thus, this provides the motivation to utilize the tannate salt of carbetapentane. Again it is pointed out that applicant has not submitted evidence of the unexpectedness of the instant invention since it is the examiner's position that the prior art suggest such as combination.

In regards to the exemplification of carbetapentane, the examiner points out that the rejection is made under obviousness, wherein the art has to suggest the instant invention. The prior art does not have to exemplify the instant invention; otherwise it would be rejected as an anticipatory reference.

In regards to applicant's arguments that the references are wholly concerned with a different problem, the examiner points out that the use of a patent is not limited to what the patentees describe as their invention or the problems with which they are

concerned, i.e. taste masking. They are part of the literature of all they contain, i.e. the teaching of an expectorant and an antitussive. See In re Heck.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., guaifenesin in an immediate dosage and the antitussive carbetapentane in an extended release dosage) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Thus, the entire argument of differential release is moot and groundless.

The rejection of claims 15-30 under 35 U.S.C. 103(a) as being unpatentable over WO 96/22762 by itself or in view of Chopdekar et al (5,663,415) in further view of Sims et al (5164398) is maintained.

WO teaches a taste-masked pharmaceutical composition. Example II teaches a syrup composition containing 0.1323% dextromethorphan HBr, 1.3230% guaifenesin, and other pharmaceutical excipients. Examples of antitussives taught are dextromethorphan, cholpendianol, carbetapentane, etc. and their salts. See page 4, lines 24-29. The reference also teaches the method of reducing or abating the symptoms associated with the common cold, respiratory disorders, etc. see page 1, lines 33-36. WO teaches tablets or liquid dosage forms. See page 5, lines 25-27.

Chopdekar et al teach antihistamine tannates since this form is stable and may be administered in its form without any side effects. See column 1, lines 15-18. The

antihistamine reacted with the tannic acid may be carbetapentane, among others. See column 3, line 3.

The references do not teach the dosage range of the antitussive.

Sims et al teach a pharmaceutical composition containing an analgesic, an antitussive, and expectorant for the relief of cough and cold symptoms (co. 1, lines 30-65). Sims teaches dextromethorphan or carbetapentane or its salt including tannate as the antitussive agent (col. 2, line 39). Guaifenesin is taught as one of the expectorants that can be used. Sims teaches the composition in the form of a tablet or suspension (col. 3, lines 40-41). The antitussive is utilized in the amount of 1-50 mg depending on the specific antitussive used and the expectorant in the amount of 100-1000 mg. See column 3, lines 30-40.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Sims teachings and utilize the instant dosage ranges. One would be motivated to utilize the instant ranges since Sims teaches this is the suitable and conventional range of the cough agents in cold remedy formulations.

In regards to the method of administering the tablets twice-a-day, it is deemed obvious to one of ordinary skill in the art to effective dosage amount by either administering the entire one-day dosage of the medication at one time or dividing it into multiple dosages since the criticality lies in administering the "effective and maximum" dosage rather than how many times it is administered. Further, note that in the composition claims, the preamble "twice-a-day therapeutic composition" is not given patentable weight since it is intended use.

Response to Arguments

Applicant argues that Sims teaches the range of the antitussive is dependent on Sim's analgesic. Applicant argues that the instant dosage is a twice a day dosage.

Applicant's arguments have been fully considered but they are not persuasive. Nowhere does Sims state that the dosage of the antitussive is dependent on the analgesic as asserted by applicant. In fact, Sims states that the dosage of the antitussive selected from carbetapentane, caramiphen, and dextromethophan, depends on the particular antitussive employed. The manipulation of concentration of a particular drug does not impart patentability since the dosage depends on an array of factors such as the symptoms to be treated, the particular drug employed, etc. The examiner relies on Sims to teach the instant amounts of guaifenesin and carbetapentane are known in the art. It should be noted that Sims also teaches the functional equivalency of dextromethophan and carbetapentane.

Lastly in regards to the twice-a-day dosage, firstly it is pointed out that applicant's amendment to the product claim is rejected under indefiniteness. It is should be noted that recitation of how many times a product should be taken in a claim directed to a product, is intended use recitation and is not given patentable weight regardless of it occurring in the body of the claim or the preamble. In regards to the method claims, the recitation of taking the composition twice a day is deemed an obvious parameter absent unexpected results, since one may take a daily effective dose at one time or twice, depending on what is desired, since the criticality lies in the amount administered within

a given day. Further, it is well known in the flu and cold art to take a cold tablet twice a day. This is not a new concept as argued by applicant.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-242-0614. The examiner can normally be reached on M-F (8:00-5:00) alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG

June 4, 2004

MICHAEL G. HARTLEY
PRIMARY EXAMINER